

Product Brief Form for HyClone Bioprocess Containers

Dear Customer,

As an ISO9001 certified company, we are anxious to provide you with the exact product that you wish to order. This document is a form for defining your product, it's packaging, testing and other important information. Please provide the information request as completely and accurately as possible, and sign and date the approval below.

1- PRODUCT DESCRIPTIONSEE ATTACHED PICTURE**2- DESIGN INTEGRATION**

Intended use:

TO ACT AS A DISPENSABLE TANK. THIS BAG WILL BE USED
TO STORE PMU MATERIAL, INKENSE CELLS FROM, STORE FINAL ANTIGEN

Chemical Compatibility Requirements:

BPL, FORMALIN, BEI

Shipping and Handling Requirements:

GAMMA IRRADIATION PRIOR TO SHIPPING 25-55K
NORMAL SHIPPING PRACTICES

Other Special Requirements:

MAY HAVE TO BE SHIPPED WITH MEDIA - NEED TO VALIDATE
SHIPPING METHOD

3- DETAILSStorage Temperature 21 °C IN EMPTY STATEWorking Temperature 14-37 °CHazardous/Corrosive Materials? ✓ yes no BPL / BEI / FORMALINFlow Rate Requirements This will be based on air pump settings and theUsage per year 400-1000

BASED ON USAGE BETWEEN
VINEYARD / MBL. MAY
INCREASE WITH MEDIA
PURCHASES.

bag being designed w/ 3/8x5/8
tubing.

TISSUE CULTURE MAIN/VINEYARD
HARVEST

USG

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4- Quality Control Release Tests

Seam Pull
Hydrostatic port test
Film Thickness
100% visual inspection for compliance to drawing

5- Certificate of Analysis Requirements

Irradiation Dose

Comments on QC and C of A criteria POSSIBLY A CERTIFICATE OF CONFORMITY

6- LIABILITY

The product shall be inspected by HyClone before shipping and by the customer upon receipt of shipment for any defects. HyClone's only liability to the customer for any product that HyClone determines was defective at the time of shipment from HyClone shall be 1- replace the product at no charge or 2- refund the amount paid. Customer hereby acknowledges that the product is being manufactured in compliance with specifications provided by the customer and the customer hereby agrees to indemnify and hold harmless HyClone against any action for infringement such as patent, trademark or copyright infringement arising from the manufacture, use or sale of the product.

7- CONCURRENT STATEMENT

HyClone's products are designed to meet quality standards based on current Good Manufacturing Practices (cGMP). Concurrent use or allowance of products to be delivered to the customer prior to final release by Quality Assurance violates cGMP. HyClone is committed to compliance.

Additional information or comments: N/A

CUSTOMER APPROVAL SECTION

Company MAINE BIOLOGICAL LABS Sales Rep Susan Henderson

Signature of Responsible

Party PIES MUSCH

Date 8-5-31-91

Address: (Drawings for approval will be sent here)

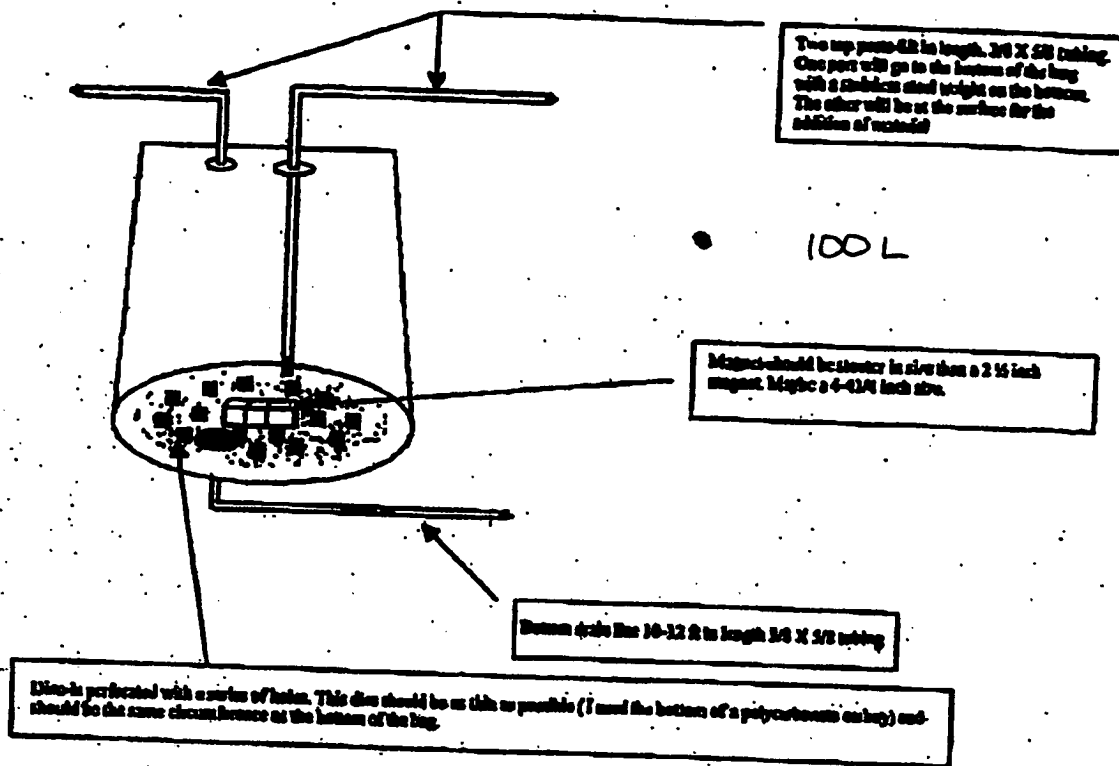
Attention:

Fax:

Phone:

Email

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